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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	SD-50003USP6	6174

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
06/30/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
Legal_Patents@abbott.com

Office Action Summary	Application No.	Applicant(s)	
	08/960,557	CEFALI ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,32,35,36,38,41,42,44,62 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,32,35,36,38,41,42,44,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-29-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment, remarks and terminal disclaimers all dated 4-8-08 and IDS dated 4-29-08 is acknowledged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-8-08 has been entered.

Status of Claims

Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are pending.

Examiner notes that the Remarks submitted with the above amendment states that claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 are pending. However, the amendment presented on 4-8-08 canceled claims 34 and 40. It appears that the claim limitation "evening or at night" of previously presented claims 34 and 40 is now introduced into claim 29 and accordingly claims 34 and 40 have been canceled.

Claim Rejections - 35 USC § 112

2. Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. A review of the instant specification on pages 6, lines 21-25, page 20, lines 3-16 and table II on page31 reveals that the instant claim limitations "for achieving a balanced lipid alteration in a patient in need thereof", "at least two formulations comprising" are not supported by the instant specification with respect to 500 mg and 1000 mg. In other words, while the new claim limitations are supported with at least two 750 mg formulations to achieve a daily dose of 1500 mg, the specification (at the above cited places) do not appear to support the at least two with respect to 500 mg and 1000 mg to achieve a daily dose of 1500 mg. Specifically, on page 20 of the specification it is stated that two tablets of 500 mg for a 1000 mg dose, two tables of 750 mg for 1500 mg dose and 2 tablets of 1000 mg for a 2000 mg dose, which is not the same as that claimed i.e., "at least two intermediate release formulations comprising 500, 750 or 1000 mg of nicotinic acid and a swelling agent to obtain a dose of at least 1500 mg". Further, the at least two tablet limitation on page 20 does not appear to be associated with the claimed "for achieving a balanced lipid alteration in a patient in need thereof". Hence, the claims lack written description support.

3. In response to that amendment, the rejections previously of record have been withdrawn and the following new rejection has been applied to the pending claims:

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5260305 to Dennick in view of US 5268181 to O'Neil ('181).

6. Dennick teaches a combination of cholesterol lowering drugs that include niacin, of the instant claims, for effectively lowering cholesterol levels, such as LDL and for treating hyperlipiemia (col. 2). Dennick teaches niacin in an amount ranging 75 mg to 2000 mg (col. 3, L 49-63), in a single or divided dosage forms. For the claimed swellable polymers, Dennick gelatin, starch etc (col. 4, L 37-40). While Dennick does not state 1500 mg in a single dose, the range of 75 -2000mg includes the claimed 1500 mg because Dennick teaches starting with a low dose and working up to higher concentrations so as to achieve a desired effect (col. 3, l 64-67). Thus, administering a dose of 1500 mg would have been within the scope of a skilled artisan with an expectation to achieve the desired treatment for elevated cholesterol levels. Dennick fails to teach administering at evening or night.

7. '181 teach a composition comprising niacin in an amount as high as 750 mg (see examples), for the treatment of hyperlipidemia (abstract, col. 2). The composition is administered in the evening similar to the instant claims. '181 teach the same delivery system as that described in the instant claims i.e., HPMC, magnesium stearate etc (see examples). '181 teach administering niacin composition in a single dose between 8 -10 pm, preferably ay evening or bedtime (col. 2, L 35-55). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to administer the

niacin composition of Kuhrts at evening or night suggested by '181, because '181 teaches that administering in the evening or at bedtime enables achieving niacin levels during the day when the levels are effective to substantially lower the levels of said serum lipids or lipid components which are primarily nocturnally biosynthesized. Hence a skilled artisan would have expected to achieve the balance of cholesterol levels without any associated side effects such as hepatotoxicity and yet a prolonged release of niacin.

The terminal disclaimers filed on 4-8-08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,080,428, 6,129,930, 6,469,035, 6,406,715, 6,746,691, 6,818,229 and 7,011,848 and application no. 10/444,145 have been received. The terminal disclaimers will be processed and Applicants will be notified in the next action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
Art Unit 1611
June 23, 2008